**MBARARA UNIVERSITY OF SCIENCE AND TECHNOLOGY**

**RESEARCH ETHICS COMMITTEE**

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SERIOUS ADVERSE EVENT REPORT

Protocol Number: |\_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ Date: |\_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_

Protocol title: |\_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_

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Investigator’s name: |\_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ Telephone #: |\_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_

Name of Institution: |\_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_

Sponsor’s name: |\_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_

Study site: |\_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_

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| Name of study medicine or device: |  |
| Onset date: |  |
| Report date: |  |
| Initial or follow-up |  |
| Sponsor’s name: |  |
| Date of first issue: |  |
| Subject’s identification number: |  |
| Age and sex of subject: |  |
| History of subject: |  |
| Laboratory findings: |  |
| Description of Serious adverse event |  |
| Seriousness of event: | \_\_ Death  ⬜ Life Threatening  ⬜ Hospitalization –⭘ initial ⭘ prolong  ⬜ Disability / Incapacity  ⬜ Congenital Anomaly  ⬜ Other………………………………… |
| Relation of event to drug, device, or study | \_\_ Not related  ⬜ Possibly  ⬜ Probably  ⬜ Definitely related  ⬜ Unknown |
| Details of treatment received |  |
| Recommended changes to the protocol |  |
| Recommended changes to the consent form |  |
| Name and date of reporter |  |